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| 10/731,547 | 12/09/2003 | Andrzej J. Chanduszeko | 106586-154 US2 | 4546 |
| 23483 | 7590 | 12/08/2008 | | |
| WILMERHALE/BOSTON 60 STATE STREET BOSTON, MA 02109 | | | EXAMINER RYCKMAN, MELISSA K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3773 | |
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| | | | 12/08/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/731,547 | Applicant(s) CHANDUSZKO ET AL. | |
| | Examiner MELISSA RYCKMAN | Art Unit 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-14,17-22 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-14,17-22 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/16/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/18/08 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicant claims "the first and second loops together" and "the third and fourth loops together" these are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1,4-10,14, 17-19 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Forber et al. (U.S. Patent No. 5,733,294).

Claim 1:

Forber et al. teaches an apparatus comprising: a patent foramen ovale (PFO) closure device having a deployed configuration for providing compressive force to septum primum and septum secundum and including: a central body (125) for extending through the PFO (Fig. 8), wherein the central body is elongated and substantially linear and extends along a longitudinal axis of the device, a first end cap (123), and a second end cap (127); a first wire and a second wire (122, col. 5, ll. 57-59) extending from the first end cap to the second end cap; the first wire and the second wire (122) defining first and second loops on one side of the PFO (Fig. 8), each of the first and second loops (132) extending from the central body to the first end cap (Fig. 8), and third and fourth loops on the other side of the PFO (130), each of the third and fourth loops extending from the central body to the second end cap (Fig. 8), each of the first and second loops (132) defining a first plane substantially parallel to septum primum and septum secundum, the first and second loops cooperating with the central body (Fig. 7, the loops move when the central body moves) apply a force, perpendicular to the first plane, to one overlapping layers (the septum is capable of being in an overlapping arrangement) of septum primum and septum secundum, each of the third and fourth loops defining a second plane substantially parallel to septum primum and septum secundum such that the third and fourth loops operating with the central body (Fig. 7, the loops move when the central body moves) apply a force, perpendicular to

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the second plane, to overlapping layers (the septum is capable of being in an overlapping arrangement) of septum primum and septum secundum (Fig. 8), wherein the first and second wires are not overlapped by another wire in the first and second planes when in the deployed configuration (wires are 22, the overlaps are by bands col. 3, ll. 42-54, therefore the first and second wires are not overlapped by other wires, they are overlapped by bands).

Claim 4:

Forber et al. teaches there are three or more loops on each side of the PFO (Fig. 6).

Claim 5:

Forber et al. teaches the central body (125) and the first (123) and second (127) end caps are oriented in a line substantially perpendicular to septum primum and septum secundum (Fig. 8).

Claim 6:

Forber et al. teaches the device has a collapsed configuration for delivery through a catheter (capable of being delivered through a catheter).

Claim 7:

Forber et al. teaches the device includes nitinol (col. 3, ll. 24).

Claim 8:

Forber et al. teaches the device includes a shape memory polymeric material (col. 3, ll. 24,25).

Claim 9:

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Forber et al. teaches the device is made from a shape memory material with properties such that the device, when delivered into a body, has a phase transition and assumes the deployed configuration (col. 5, ll. 58-60).

Claim 10:

Forber et al. teaches the device is retrievable, redeployable, and repositionable (the device is capable of being retrievable, redeployable, and repositionable).

Claims 14,17-19:

Forber et al. teaches a method comprising delivering the PFO closure device through a catheter (col. 4, ll. 60) to a PFO (col. 5, ll. 66), wherein the device includes a shape memory material (col. 3, ll. 24).

Claims 25-28:

Forber teaches the first and second loops together have a first axis that bisects the first and second loops, the first axis being adapted for alignment with a longitudinal axis defined by the septum primum and secundum (Fig. 3).

Forber teaches the third and fourth loops together have a second axis that bisects the third and fourth loops, the second axis being adapted for alignment with a longitudinal axis defined by the septum primum and secundum (Fig. 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11, 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forber et al. in view of Huebsch et al. (US 6117159)

Forber et al. teaches all limitations of preceding dependent claim 1 but fails to teach wherein material is present over the first and second loops or the third and fourth loops for promoting tissue ingrowth. Huebsch teaches a septal defect closure device wherein the device is bioresorbable covered in a material to promote tissue ingrowth in order to help with stabilization of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Forber with a material to promote tissue ingrowth in order to help with stabilization of the device.

Claims 12, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Forber et al. and Huebsch, and further in view of Neuss et al (US 6355052).

The combination of Forber et al. and Huebsch teaches all limitations of preceding dependent claims 1 and 11, and further teaches delivering the PFO closure device through a catheter (Forbes, col. 4, ll. 60) to a PFO (Forbes, col. 5, ll. 66), and drawing the device back into the catheter (Huebsch, col. 6, ll. 17-20), but fails to teach wherein the loops are made of a bioresorbable material. Neuss teaches a PFO closure device, wherein the loops are made of a bioresorbable material such to avoid complications associated with permanently implanted foreign bodies. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Forber et al. and Huebsch as with bioabsorbable material such to avoid complications associated with permanently implanted foreign bodies. It would have been obvious to one of ordinary skill in the art to have drawn the device back into the catheter, as the device may not need to remain in the body as the body heals.

Response to Arguments

Applicant's arguments filed 9/18/08 have been fully considered but they are not persuasive. The applicant generally argues:

- Forber does not teach the first and second wires are not overlapped by another wire

The examiners position is that Forber teaches using wires, 22 for the first and second wires, and are overlapped by bands, they are not overlapped by wires.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773